Remarks

Amendments

Claims 13-16 are pending in the application. Claims 13, 14, and 16 have been amended as shown above. No claims have been added.

Claim 13 has been amended to recite that the drug delivery path preservation means comprises a coating that resists fibrous occlusion of the drug delivery ports. Claim 14 has been amended to recite that the coating comprises poly(glycine-valine-glycine-valine-proline). Claim 16 has been amended to recite that the coating comprises a material selected from the group consisting of connective tissue growth blocker, C-Proteinase blocker, prolyl hydroxylase blocker, poly(glycine-valine-glycine-valine-proline), and polylacticglycolic acid microspheres including dexamethasone.

Each of these amendments is supported by the specification as originally filed. For Example, the amendment to claim 13 is supported at paragraph 0049 of the application as published (2004/0034338 A1); the amendment to claim 14 is supported at paragraphs 0049 and 0053 of the application as published; and the amendment to claim 16 is supported at paragraphs 0049 through 000055 of the application as published.

It is submitted that these amendments do not introduce any new matter and are fully supported by the specification. It is further submitted that these amendments overcome all of the rejections and place the claims in condition for immediate allowance. Entry of the amendments, reconsideration of the rejections, and allowance of all of the claims is requested.

Discussion

The Rejection of Claim 14 Under 35 U.S.C. 112, First Paragraph

Claim 14 has been rejected under 35 U.S.C. 112, first paragraph. Applicants submit that this rejection has been rendered moot.

The specification teaches that fibrous occlusion of the drug delivery ports can be resisted by the use of a variety of coatings. See paragraphs 0049 through 0055 of the published application. Poly(glycine-valine-glycine-valine-proline) is one of these chemical coatings. As claim 14 now recites that the catheter have a coating of poly(glycine-valine-glycine-valine-proline), it is submitted that the rejection of claims 14 under 35 U.S.C. 112, first paragraph has been overcome and should be withdrawn.

The Rejection of Claim 16 Under 35 U.S.C. 112, Second Paragraph

Claim 16 has been rejected under 35 U.S.C. 1112, second paragraph. Applicants have amended this claim to recite that the coating is selected from a specified group of materials. It is submitted that this amendment overcomes the rejection of claim 16 under 35 U.S.C. 112, second paragraph and that this rejection should be withdrawn.

The Rejection of Claims 13, 15, and 16 Under 35 U.S.C. 102(b)

Claims 13, 15 and 16 have been rejected under 35 U.S.C. 102(b) over U. S. Patent 5,041,107 (hereinafter Heil). Applicants traverse this rejection and submit that Heil does not anticipate these claims.

With regard to Heil, the Examiner argues that it discloses a plastic membrane bonded to the catheter body; that the membrane that is tightly conformed to the body; and that the membrane covers the slits. He further argues that the material of the membrane is chosen so as to have a molecular weight that is a total barrier against high molecular weight blood clot forming substances such as fibrinogen and thrombin. He concludes that this means that the membrane is explicitly disclosed as being a part of the drug delivery port and that the substance for resisting fibrous occlusions is in the port. Applicants submit that the Examiner's reasoning has been rendered moot by the amendments to the claims.

Claim 13, 15, and 16 require that the drug delivery path preservation means comprise a coating of a composition that resists occlusion of the drug delivery ports. The coating employed in the present invention interacts with occlusion-forming substances to prevent the formation of occlusions in the ports.

Heil teaches the use of a plastic film that is attached to the catheter at two discrete points. The plastic film **covers** the ports. Rather than interacting with clot-forming substances, this plastic film provides a barrier that physically blocks the clot-forming substances from ever reaching the ports. This physical barrier prevents the build-up of clots in the ports by preventing clot-forming substances from ever reaching the ports. Thus, Heil teaches a different structure and mechanism than is required by the present claims.

The present claims employ a coating on the catheter. The coating does not simply block clot-forming substances from reaching the ports. Rather, the coating interacts with the substance(s) that form fibrous occlusions to resist the formation of such occlusions.

Since Heil fails to teach either the claimed structure or mechanism, it fails to support the rejection of these claims under 35 U.S.C. 102(b).

Claims 14 and 16 are not anticipated by Heil for another reason. These claims respectively recite that the coating comprises a specific material and a specific group of materials for interacting with occlusion-forming materials to resist the occlusion of the ports. Heil fails to disclose the use of these materials and therefore cannot support the rejection of these claims under 35 U.S.C. 102(b).

The Rejections of Claims 13-16 Under 35 U.S.C.103(a)

Claim 13-16 have been rejected under 35 U.S.C. 103(a) over U.S. Patent 5,752,930 (Rise) in view of U.S. Patent 6,970,741 (Whitehurst). Claims 13-16 have also been rejected under 35 U.S.C. 103(a) over U.S. Patent 5,752,930 (Rise) in view of U.S. Patent 6,567,705 (Stokes).

Rise (the primary reference) is discloses a technique for infusing equal volumes of agents to spaced sites in a patient and a device for accomplishing this result. As admitted by the Examiner, Rise fails to disclose a drug delivery path preservation means. In fact, Rise is silent with respect to such an element. Thus Rise fails to recognize the need for such an element.

Whitehurst discloses an implantable system for monitoring, preventing, and treating rejection of transplanted organs. The system monitors the impedance and impedance changes of an allograft so that appropriate levels of immunotherapy agents may be delivered to the patient to cause appropriate attenuation of the immune system and prevent rejection of a transplanted organ.

Stokes discloses a system and method for delivering an ion channel protein genetic material (e.g., sodium ion channel protein, etc,) to a site in a patient's heart that is adjacent to an electrode so as to increase the expression of the same, thereby enhancing the cardiac signal amplitude and enabling improved sensing of cardiac signals by an implanted pacemaker. A predetermined amount of a medication may also be delivered by the system. These medications can include steroids to control inflammation.

The Examiner asserts that the Whitehurst and Stokes references (the secondary references) each disclose that it is known to have a drug delivery path preservation means for delivering a substance to the ports of the system for resisting fibrous occlusion of the ports. He further asserts that it would be obvious to modify the device of Rise to include the drug

delivery path preservation means of either of the secondary references. Applicants traverse this reasoning.

Contrary to the Examiner's assertion, neither of the secondary references discloses or suggests the use of a drug delivery path preservation means. The secondary references only disclose a system for delivering an agent to a patient to provide a specific therapeutic effect in that patient by transporting that agent **through** a catheter to a specific site in the patient. There is no disclosure in either reference that this agent should remain with the catheter rather than being delivered to the patient and remaining with the catheter. There is no disclosure in either reference that the agent should be used to resist the fibrous occlusion of drug delivery ports in a catheter.

Neither of the secondary references provides any reason to employ a drug path preservation means on a catheter. In fact, the use of any of the agents disclosed in the secondary references as coating on a catheter to provide a drug path preservation means is contrary to the intent of the secondary references. The intent of the secondary references is to transport the agent to the patient so that it can provide a desired therapeutic benefit to the patient. The present invention, however, does not deliver the drug path preservation means to the patient. Rather, it retains the delivery path preservation means on the catheter so that it can interact with substances that form fibrous occlusions in the drug delivery ports of the catheter thereby enhancing the functionality of the catheter.

The primary reference (Rise) also fails to provide any reason to employ a drug path preservation means. As noted above, Rise is silent with respect to the use of such an element. Consequently, Rise does not recognize that there is a problem to be solved and therefore cannot suggest a solution for such a problem. Moreover, Rise teaches that the delivery of desired agents through the infusion slits of his device is accomplished by the use of differential pressure. When the agent is to be delivered, a sufficiently high pressure is employed to overcome the fluid resistance that prevents the flow out of the elution openings. See column 1, line 43 through column 2, line 17, especially column 1, lines 55 through 61. Thus Rise clearly sees no reason to modify his device to add a drug path preservation means as is required by the present claims.

Based on these amendments and arguments, it is submitted that the combination of the primary reference with either of the secondary references does not support the rejection of claim 13-16 under 35 U.S.C. 102(a).

Conclusion

Based on the preceding comments, Applicants submit that they have shown that claims 13-16 are patentable over the cited references. They request reconsideration of the rejections and allowance of all claims.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

Kagan Binder, PLLC

Dated: December 12, 2007

By: James V. Lilly

James V. Lilly, Reg. No. 27,817
Customer Number 33072
Phone: 651-275-9844
Facsimile: 651-351-2954

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THIS WILL ACKNOWLEDGE RECEIPT OF THE FOLLOWING IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

- Response and Amendment After Final Rejection (7 pgs)
- Return receipt postcard

Applicant:	Thierfelder, et al.
Serial No.:	10/636,182
Filed:	August 7, 2003
For:	DRUG DELIVERY DEVICE AND METHOD
Docket No.:	AMS0091/US
Date Mailed:	December 12, 2007

JVL/jj